K033197

MED Corporation

MAY 1 3 2004

Special 510(K)

510(K) Summary

Medical Electronic Devices Corporation

Modified Medical Electronic Devices Corporation
$POCD_{EB}$ Pulsed Oxygen Conserving Device

October 1, 2003

Submitter Information:

Medical Electronic Devices Corporation
2807 Oregon Court, D6
Torrance, California 90503

Submitter's Name: Thomas Wenzel
Phone: (310) 618-0306

Device Name:

Proprietary Name: Inogen Satellite Conserver

Common Name: Oxygen Conserver

Classification Name: Noncontinuous Ventilator

Predicate Device Equivalence:

Substantial equivalence is claimed to the Medical Electronic Devices Corporation unmodified $POCD_{EB}$, cleared for commercial distribution per K023420 and the Airsep Lifestyle Oxygen Concentrator K020324.

Device Description:

The Inogen Satellite Conserver intended to be used as an accessory to the Inogen One Oxygen Concentrator (K032818). The device uses the Inogen One Oxygen Concentrator as its oxygen supply and is connected by an oxygen supply tube. The Inogen Satellite Conserver is a battery operated electronic device that is microprocessor controlled and contains a breath sensor and normally closed valve. Upon detecting the beginning of inhalation, the device delivers a bolus of oxygen that is equivalent in most users to 1 to 5 liters per minute constant flow, depending on the flow setting.

Intended Use:

The Inogen Satellite Conserver is intended for use to conserve oxygen for patients prescribed supplemental oxygen and use nasal cannulas and an oxygen concentrator.

Comparison of Technological Characteristics:

The Inogen Satellite Conserver has the same technological characteristics as the predicate device, i.e. the $POCD_{EB}$. The electronic circuitry of the device is identical to the $POCD_{EB}$. There are physical differences in the labeling and device enclosure needed to differentiate the two products.

The software has been modified in order to control the valve to deliver the appropriate size bolus of oxygen. This dosing algorithm is based on the 5 switch settings and the oxygen supply pressure of the Inogen One Oxygen Concentrator. This dosing algorithm is identical to the algorithm used in the predicate device, the Airsep Lifestyle Oxygen Concentrator.

Summary of Testing:

Appropriate performance, mechanical, and electrical testing was performed to demonstrate that the Inogen Satellite Conserver would perform as intended.

Conclusions:

Based on the above, we concluded that the Inogen Satellite Conserver is substantially equivalent to currently marketed devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 3 2004

Mr. Thomas Wenzel
President
Medical Eletronic Devices, Incorporated
2807 Oregon Court Unit D6
Torrance, CA 90503

Re: K033197
Trade Name: Inogen Oxygen Conserver
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NFB
Dated: March 5, 2004
Received: March 8, 2004

Dear Mr. Wenzel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033197

Device Name: Inogen Satellite Conserver

Indications For Use: The Inogen Satellite Conserver is intended for use to conserve oxygen for patients prescribed supplemental oxygen and use nasal cannulas and an oxygen concentrator.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033197